

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of efficacy of herbal ointment containing aqueous extract Scrophularia Straita Boiss, Honey , Sativa Nigella oil ,Mazo, Apple Vinegar in treatment of ulcers diabetes

Protocol summary

Study aim

Evaluation of efficacy of herbal ointment containing aqueous extract Scrophularia Straita Boiss, Honey , Sativa Nigella oil ,Mazo, Apple Vinegar in treatment of ulcers diabetes

Design

This study is a clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients.

Settings and conduct

This study is performed in patients referred to Imam Reza Hospital and Imam Khomeini Hospital in Kermanshah. Blinding is done for all patients and clinical caregivers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with diabetic ulcer
Exclusion criteria: Pregnant women - Children - People undergoing chemotherapy - People receiving corticosteroids. - Patients suffering from liver and kidney failure.

Intervention groups

In the intervention group, wound treatment with ointment, herbal detergent and routine dressing In the control group, perform routine puncture and wound routine

Main outcome variables

Wound severity Wound area Wound site Wound depth Exodus Type of texture Pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201213049703N1**
Registration date: **2021-02-10, 1399/11/22**
Registration timing: **prospective**

Last update: **2021-02-10, 1399/11/22**

Update count: **0**

Registration date

2021-02-10, 1399/11/22

Registrant information

Name

Toraj Ahmadi Jouybari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 83 3727 2049

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t.ahmadijouybari@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of herbal ointment containing aqueous extract Scrophularia Straita Boiss, Honey , Sativa Nigella oil ,Mazo, Apple Vinegar in treatment of ulcers diabetes

Public title

Effect of herbal ointment in treatment of ulcers diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with diabetic ulcers

Exclusion criteria:
Pregnant women Patients suffering from liver and kidney failure Children People undergoing chemotherapy People receiving corticosteroids.

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization and assigning people to groups The random number function is used using Excel software as follows: First, in a column, the groups are entered as A, B and below. In the opposite column, random numbers are generated using the RAND command. In the next step, using the sort command, random numbers are generated from small to large or vice versa, which causes the order of the groups, A, B, to be changed. Using the new order, people are assigned to different groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Herbal ointments and routine treatment ointments are designed to be the same in terms of color and odor so that they are not recognizable to the patient and the caregiver. And only the statistical analyst should be aware of the ointment used.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Kermanshah, Shahid Beheshti Blvd., Kermanshah University of Medical Sciences

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Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-04-11, 1399/01/23

Ethics committee reference number

IR.KUMS.REC.1399.073

Health conditions studied

1

Description of health condition studied

Ulcers diabetes

ICD-10 code

E11.4

ICD-10 code description

Type 2 diabetes mellitus with neurological complications

Primary outcomes

1

Description

PUSH Score

Timepoint

Every week until the 12th week

Method of measurement

Based on the characteristics of diabetic ulcers

Secondary outcomes

1

Description

Wound area

Timepoint

Every week until the 12th week

Method of measurement

With a caliper, the dimensions of the wound, including the length and width of the wound, are measured and its area is calculated

2

Description

Wound depth

Timepoint

Every week until the 12th week

Method of measurement

Wound depth is measured with forceps and calipers

Intervention groups

1

Description

The herbal ointment of the design containing thirsty

plant extract, honey, black seed oil, mazo will be provided to the patients of the intervention group in the form of ready-to-use tubes without printing of the design. Contains thirst extract, apple cider vinegar and normal saline, washed and dried with sterile gauze. The herbal ointment is then applied to the wound with a watering can and fixed with a four-layer sterile dry gauze with anti-allergy adhesive. Changing the dressing and using the ointment should be done once a day for the necessary time. (Depending on the patient's condition until complete treatment)

Category

Treatment - Other

2**Description**

Liam topical ointment (manufacturer of Mehr Miracle Researchers) containing chamomile extract, 8% cow's eye, 13% beeswax and 17% honey as a routine ointment of Imam Khomeini Hospital in Kermanshah in the form of ready-to-use tubes without printing. Patients in intervention group 2 will be included. The procedure will be performed by washing the wound and surrounding tissues with normal saline solution and drying them with sterile gauze. Liam ointment is then applied to the wound with a watering can and fixed with a four-layer sterile dry gauze with anti-allergy adhesive. Changing the dressing and using the ointment should be done once a day for the necessary time. (Depending on the patient's condition until complete treatment)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam khomeini Hospital

Full name of responsible person

Toraj Ahmadi Jouybari

Street address

Kermanshah -Naghlieh Ave- Imam Khomeini Hospital

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Kermanshah

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Kermanshah

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Phone

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Email

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2**Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Toraj Ahmadi Jouybari

Street address

Kermanshah -Parastar Blvd- Imam Reza Hospital

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Province

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Phone

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Email

dr.ahmadi_jourbari@yahoo.co

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Reza KhodaRahmi

Street address

Shahid Beheshti Blvd, Kermanshah University of Medical Sciences

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rkhodarahmi@mbrc.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Toraj Ahmadi Jouybari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

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Email

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Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Toraj Ahmadi Jouybari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Email

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Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Haji Ghorban Ghibadi

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Results can be shared after not identifying people.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

All interested people

Under which criteria data/document could be used

For the use of other researchers

From where data/document is obtainable

Toraj Ahmadi Jouybari dr.ahmadi_jouybari@yahoo.com

What processes are involved for a request to access data/document

1. Send request to email 2. The purpose of the data request should be clear. 3. If approved by the main executor, action will be taken immediately

Comments